Flexible Bio-therapeutic Infrastructure RFI, SN08-14; Responses due: March 6, 2008, 4:00pm ET; POC: Dr. Michael Callahan, DARPA/DSO; Phone: (571) 218-4596, Fax: (703) 807-4945

DESCRIPTION

The Defense Sciences Office (DSO) of the Defense Advanced Research Projects Agency is seeking the demonstration of innovative concepts and technologies for just-in-time flexible bio-therapeutic infrastructure resources at 10,000-dose scale (e.g., 90 μg/dose vaccine, 400 mg/dose mAb). The goal of this RFI is to identify portable, minimal footprint technologies that satisfy the dual requirements of extreme low cost development and high capacity production for therapeutic vaccines or monoclonal antibodies within an abbreviated timeframe.

Specifically, this RFI seeks information on the following relevant technologies and capabilities:

1. Flexible systems: Single use, integrated and automated solutions that meet the metabolic demands of diverse, engineered, and transiently expressed protein expression systems. DARPA is interested in new technologies that exceed current capabilities used to support the growth of substrates for diverse expression systems including prokaryotes, yeast, fungus, and algae. DARPA is not specifically interested in systems used for mammalian cell-based protein expression.

2. Ultra-low cost: Reduced costs associated with protein expression systems, such as reduced bioreactor equipment costs, operation costs, media requirements and independence from purpose-built facilities and infrastructure. The low cost of materials would allow for the rapid conversion of the bioreactors to on-demand production of biological countermeasures.

3. Current Good Manufacturing Practices (cGMP): Capabilities and plans for quality control measures, as well as mitigation strategies.

4. Deployment: Minimal reliance on local resources, human capital, and critical reagent supply, as well as a minimal need for user expertise (typical of a Combat Support Hospital).

RESPONSE INFORMATION

DARPA appreciates responses from all capable and qualified sources, including but not limited to, universities, university affiliated research centers, and private or public companies. To ensure that all technically relevant aspects of the program are fully addressed in an integrated approach, teaming with groups with complementary areas of expertise is highly encouraged.

When responding to this RFI, please include examples of the bioreactor successfully deployed and expressing protein products. Please indicate the titer, type of cell, type of culture (suspension, or matrix dependent), type of culture medium (batch, fed batch, or continuous), if the process is cGMP, how many batches are produced annually, bioreactor structural

composition, working volume, aeration technologies, stirring techniques, media addition, variables controlled inside the bioreactor, cost estimates of components, materials, and media, and the mechanism changeover to production of a new target. Critical to this RFI is an indication of the development status of the bioreactor components.

Acknowledged technological barriers to accomplishing this goal include: heat dissipation, low cost modular purification components, precise requirements for maintaining optimal expression conditions during scale-up, and automation control.

FORMAT

Responses should adhere to the following formatting and outline instructions:

1. Format specifications include 12-point Times New Roman font, single-spaced, single-sided, 8.5 by 11 inch paper, with 1-inch margins. All submissions must be electronically submitted to **Callahan@darpa.mil**, and be in one of the following formats: Microsoft Word and/or Microsoft PowerPoint.

2. Cover Page (1 page)
   a. Title.
   b. Organization.
   c. Respondents' technical and administrative points of contact (names, addresses, phones and fax numbers, and email addresses).

3. Technical description (3 pages maximum)
   a. Details on the technology and how respondents meet requirements stated above.
   b. Optional list of citations, including URLs, if available.

4. Slides (3 slides maximum)
   a. Experimental design to meet large-scale infrastructure and resources at 10,000-dose scale (e.g., 90 μg/dose vaccine, 400 mg/dose mAb).
   b. Current capabilities and demonstrated data associated with successful expression of protein products.

Respondents are encouraged to be as succinct as possible while providing astute information.

SUBMISSION

Responses to this RFI should be submitted to Callahan@darpa.mil. Please refer to the "Flexible Bio-therapeutic Infrastructure RFI" in all correspondence.

All technical and administrative correspondence and questions regarding this announcement should also be submitted to the same email address.

DARPA intends to use electronic mail and fax for correspondence regarding RFI SN08-14.

DISCLAIMERS AND IMPORTANT NOTES

This is an RFI issued solely for information and new program planning purposes; the RFI does not constitute a formal solicitation for proposals or proposal abstracts. In accordance with FAR 15.201(e), responses to this notice are not offers and cannot be accepted by the Government to form a binding contract. Submission is voluntary and is not required to propose to subsequent Broad Agency Announcements or research solicitations on this topic (if any). DARPA will not provide reimbursement for costs incurred in responding to this RFI. No classified information should be submitted. Proprietary information must be approved in advance by the Program Manager and clearly labeled as "proprietary" to be accepted. Respondents are advised that DARPA is under no obligation to acknowledge receipt of the information received, or provide feedback to respondents with respect to any information submitted under this RFI.

In the event of a BAA or other solicitation, all information not specifically noted as proprietary in response to the RFI will be considered public information. NO CLASSIFIED INFORMATION SHOULD BE INCLUDED IN THE RFI RESPONSE. It is the respondents' responsibility to ensure the material has been approved for public release by the organization that funded the research.